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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/614,150	07/11/2000	J. CRAIG VENTER	CL000728	1598

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EXAMINER

JOHANNSEN, DIANA B

ART UNIT PAPER NUMBER

1634

DATE MAILED: 11/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/614,150	Applicant(s) VENTER ET AL.	
	Examiner Diana B. Johannsen	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

FINAL ACTION

1. This action is in response to the Amendment and Response filed July 26, 2004. Claims 1, 3-5, 7-9, 11-13, and 15-16 have been amended, and claims 1-16 are now pending and under consideration. The amendments and arguments have been thoroughly reviewed, but are not persuasive for the reasons that follow. Any rejections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims. **This action is FINAL.**

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restriction

3. Applicant's election of the first 1000 transcript sequences provided in the Sequence Listing (i.e., every third sequence beginning with SEQ ID NO: 2 and ending with SEQ ID NO: 3002) in the Response of July 7, 2003 is again acknowledged.

Sequence combinations other than the combination set forth immediately above remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Election was made **without** traverse in the Response of July 7, 2003.

Claim Rejections - 35 USC § 101 and 35 USC § 112, first paragraph: Utility

4. Claims 1-16 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific, substantial and credible asserted utility or a well established utility, for reasons stated in the prior Office action.

First, the response traverses the rejection on the grounds that while the examiner has stated that Applicant's elected group of sequences appears to constitute a group of the first 1000 predicted transcripts identified in the *D. melanogaster* genome, "Applicants have not elected a group of the first 1000 predicted transcripts identified in the *D. melanogaster* genome," but rather "have elected a group of sequences that constitute substantially all of the predicted transcripts identified in the *D. melanogaster* genome as of the filing date of the instant application." The response continues that "Applicants have elected the 14,336 transcript sequences identified as "SEQ ID NOS: 2, 5, 8, 11...43001, 43004, 43007." The response continues that the claimed invention "is amenable to a wide variety of utilities that are well established in the art, depending on how the array or other detection reagent is configured," noting that groups of the elected 14,336 transcripts "can be selected from amongst, for example, transcripts that encode proteins of specific protein families..., transcripts which are encoded by *Drosophila* orthologs of known human diseases or known human drug target genes, transcripts involved in various *Drosophila* biological pathways, etc., wherein the transcripts are selected from amongst the 14,336 transcripts elected by Applicants."

These arguments have been thoroughly considered but are not persuasive.

Applicant is reminded of the following statement in their response of July 7, 2003, which was responsive to the Election/Restriction of May 7, 2003:

Applicants hereby elect SEQ ID NOS:2, 5, 8, 11...2993, 2996, 2999, 3002 (i.e., the first 1000 transcript sequences provided in the Sequence Listing and Table/Figure Sheets; the transcripts are every third sequence beginning with SEQ ID NO:2) as the combination of 1000 SEQ ID Nos that the Examiner requested Applicants to elect for search and examination.

Thus, the group of transcript sequences actually elected by Applicant does not in fact correspond to that discussed in Applicant's traversal of the instant rejection. Furthermore, the instant claims have not been amended such that they are in fact limited to such a particular group. The remainder of Applicant's arguments relate to particular groups of sequences that might potentially be selected by one of skill from amongst the 14,336 sequences alleged elected by Applicant: however, such a group of 14,336 was not in fact elected, and the instant claims are not drawn or limited, e.g., to a particular group of sequences having any of the properties or characteristics discussed in Applicant's response. Thus, as Applicant's arguments do not pertain to the elected invention, these arguments are not persuasive, and the instant rejection is maintained.

5. Claims 1-16 are also rejected under 35 U.S.C. 112, first paragraph, for the reasons stated in the prior Office action.

The response traverses the rejection for the same reasons discussed in paragraph 4, above. Accordingly, the response to those arguments applies equally herein, and this rejection is maintained.

Claim Rejections - 35 USC § 112, second paragraph

6. Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-16 are indefinite over the recitation of the phrase "the transcript sequences of SEQ ID NOS:2, 5, 8, 11....43001, 43004, 43007" in claims 1, 5, 9, and 13. It is unclear from this language as to whether the claims require the particular

sequences set forth in the recited SEQ ID Nos (i.e., the full length of SEQ ID NO: 2, the full length of SEQ ID NO: 5, etc.), or whether the claims encompass subsequences of the recited SEQ ID Nos that constitute “the transcript sequences” of those recited SEQ ID Nos. The response traverses the rejection on the grounds that “the ‘consisting’ language used” in the claims clearly limits the claims “to the particular full length-sequences set forth in the recited SEQ ID Nos.” However, this argument is not persuasive: while this argument would apply if the claims recited, e.g., “the sequences of....,” the additional requirement for “transcript” sequences suggests the possibility that subsequences containing within the recited SEQ ID Nos that correspond to transcripts could also be encompassed by the claims. Accordingly, clarification is required, and this rejection is maintained.

THE FOLLOWING ARE NEW GROUNDS OF REJECTION NECESSITATED BY APPLICANTS’ AMENDMENTS:

Claims 7-8, 11-12, and 15-16 are indefinite over the recitation of the limitation “said at least 1000 Drosophila transcripts” in each of the claims because there is insufficient antecedent basis for this limitation in the claims.

Claim Rejections - 35 USC § 102

7. Claims 1-3, 5-7, 9-11, and 13-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Brennan (U.S. Patent No. 5,474,796 A [12/1995]), for reasons stated in the prior Office action.

The response traverses the rejection on the grounds that the claims have been amended so as “to clarify that the claimed detection reagents exclusively detect the

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presence of 1000/2000/5000/10,000 or more different specific *Drosophila* transcripts,” while “the array of Brennan et al will inherently detect a wide variety of transcripts and related molecules other than the specific *Drosophila* transcripts detected by the claimed detection reagents.”

This argument has been thoroughly considered but is not persuasive. The claims under consideration are drawn to products, not to methods in which, e.g., particular steps must be employed that result in “exclusive detection” of *Drosophila*. Further, Applicant has not amended the claims in such a way so as to specifically limit the structural properties of the products encompassed thereby; rather, Applicants’ amendments to the claims have merely modified the intended use of the claimed reagents such that they are “for exclusively detecting the presence of.....”. Such recitations are only limiting of the product of the claims if they result in a structural difference between the claimed invention and the prior art (see MPEP 2111.02). MPEP 2111.02 further states that “If a prior art structure is capable of performing the intended use as recited in the preamble, then it meets the claim.” As it would be well within the ability of one of ordinary skill to employ the array of Brennan in such a way that would permit “exclusive detection” of *Drosophila*, Brennan anticipates Applicants’ invention as claimed. Accordingly, as Brennan teaches all the limitations recited in present claims 1-3, 5-7, 9-11, and 13-15, this rejection is maintained.

8. Claims 1-2, 5-6, 9-10, and 13-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Bryant et al (Proceedings of the National Academy of Sciences USA 96:5559-5564 [5/1999]), for reasons stated in the prior Office action.

The response traverses the rejection on the following grounds. The response argues that “no information is provided regarding the sequences” of the “4,500 unique *Drosophila* cDNAs” of Bryant et al, whereas the instant claims are limited to particular sequences. The response urges that “Without knowledge of the specific sequences” of Bryant et al’s microarray, the reference cannot anticipate the claims.

This argument has been thoroughly considered but is not persuasive. It is again noted that (as discussed above) the claims as written merely require a reagent/array that is capable of performed the intended use recited in the claims. This objective (of performing the recited intended use) may be achieved in any manner, using any type of method steps, etc. As the microarray of Bryant et al is clearly capable of performing the intended use recited in the claims, and as that intended use does not result in a structural difference between the claimed product and the prior art product, Bryant et al does in fact anticipate the claimed invention. Accordingly, as Bryant et al teach all the limitations recited in present claims 1-2, 5-6, 9-10, and 13-14, this rejection is maintained.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 571/272-0744. The examiner can normally be reached on Monday-Friday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached at 571/272-0745. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in dark ink, appearing to read "Diana B. Johannsen", with a long horizontal stroke extending to the right.

Diana B. Johannsen
Primary Examiner
November 1, 2004